K140631

MAY 16 2014

510(K) Summary

Submitter:	Shaser, Inc. 10 Maguire Road Building 1 Lexington, MA 02421
Contact:	Anthony Burns Senior Director of Regulatory Affairs
Date Summary Prepared:	May 13, 2014
Device Trade Name:	Lumena FH Hair Removal System
Common Name:	Light based hair removal device
Classification Name:	Powered Light Based Non-Laser Surgical Instrument with Thermal Effect. Product Code ONF
Equivalent Device:	Shaser V-MINI 2 Hair Removal System
Device Descripton:	Over-The-Counter, AC Powered, Personal Light-Based Hair Removal System. Emission activation is by fingerswitch. Device includes a limited life lamp cartridge. Overall weight of the device is 1.0 Kg, and the size is 22 x 16 x 78 cm (HxWxD). The Principle of Operation is selective photothermolysis and the Mechanism of Operation is to disable hair growth using light to preferentially heat the hair bulb. Electrical Requirement is 115-230 VAC, 50-60 Hz, 1.3A single phase.
Intended Use:	Removal of unwanted hair.
Indication for Use:	Lumena FH is an over the counter device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – IV. The Lumena FH is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.
Comparison:	The Lumena FH Hair Removal System has the same indication for uses, the same principle of operation, the same pulse energy range and wavelength range as the Shaser V-MINI 2 Hair Removal System.

	Proposed Modified Device	Predicate Device **510(k) K133201**
Manufacturer	Shaser, Inc.	Shaser, Inc.
Trade Name	Lumena FH Hair Removal System	Shaser V-MINI 2 Hair Removal System
Indications	Lumena FH is an over the counter device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – IV. The Lumena FH is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.	Shaser V-MINI 2 is an over the counter device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – IV. The Shaser V-MINI 2 is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.
'Use Classification'	OTC	OTC
Device Type	Intense Pulsed Light	Intense Pulsed Light
Wavelength range (nm)	400nm – 1200nm	400nm – 1200nm
Fluence Settings	1 = 6 (J/cm^2)	1 = 6 (J/cm^2)
	2 = 7 (J/cm^2)	2 = 8 (J/cm^2)
	3 = 8 (J/cm^2)	3 = 10 (J/cm^2)
	4 = 9 (J/cm^2)	
	5 = 10 (J/cm^2)	
Spot Size (mm)	$2cm^2$	$2cm^2$
Pulse Width (ms)	<200	<200
Time Between Flashes (sec.)	<8	<8
Source Energy	AC Mains	Battery
User Interface	LED indicator lights	LCD display with text and graphics
Control Mechanism	Microprocessor-based control	Microprocessor-based control

Nonclinical Performance Data:	Bench testing for performance verification and electrical safety testing.
Clinical Performance Data:	Label comprehension and usability test of consumers' ability to understand the instructions for use and to evaluate their ability to use the device safely in a simulated OTC home-use environment. • 150 study subjects were tested for label comprehension and 123 study subjects tested for usability. Both test populations included low literacy subjects. The results of the two tests confirm sufficient label comprehension and safe and appropriate use of the device.
Conclusion:	The results of the nonclinical and clinical performance data conclusively demonstrates that the proposed device is at least as safe and effective as the Lumena FH Hair Removal System and is a safe and effective device for the intended uses.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Shaser Incorporated
Mr. Anthony Burns
Senior Director of Regulatory Affairs
10 Maguire Road
Lexington, Massachusetts 02421

Re: K140631

Trade/Device Name: Lumena FH Hair Removal ystem
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: April 17, 2014
Received: April 18, 2014

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140631

Device Name
Shaser Lumena FH Hair Removal System

Indications for Use *(Describe)*

Lumena FH is an over the counter device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – IV. The Lumena FH is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.05.15 15:18:48 -04'00'

For BSA

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